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ORIGINAL RESEARCH ARTICLE

Teratogenic Risk Perception and Confidence in Use of Medicines in Pairs of Pregnant Women and General Practitioners Based on Patient Information Leaflets

Sofia Frost Widnes · Jan Schjøtt · Geir Egil Eide · Anne Gerd Granas

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Abstract
Objective The aim of this study was to examine teratogenic risk perceptions and confidence in the use of medicines in pairs of pregnant women and general practitioners (GPs) through assessments of medicines information texts from patient information leaflets (PILs).
Methods A questionnaire was handed out to women attending regular ultrasound examination in week 17–19 of pregnancy. The women stated name and address of their GP and questionnaires were sent to the GPs' clinic. The questionnaires contained texts regarding pregnancy from PILs for pivmecillinam, metoclopramide, paracetamol, escitalopram, Valeriana officinalis and dexchlorpheniramine. For each PIL, teratogenic risk (scale from 0: never teratogenic to 10: always teratogenic), confidence in use of medicines (yes or no) and clarity of the text (scale from 0: exceptionally clear to 3: exceptionally unclear) were assessed.
Results In total, 171 pregnant women and 74 GPs participated, of which 98 pairs were identified. Pregnant women had significantly higher perceptions of teratogenic risks and lower confidence in use of medicines compared to GPs. Differences in teratogenic risk perceptions and confidence in use were highest for escitalopram and lowest for dexchlorpheniramine, representing texts with different phrasing and length. Neither pregnant women nor GPs were confident in using Valeriana officinalis.
Conclusions Perceptions of teratogenic risks and confidence in use of medicines during pregnancy differ within pairs of pregnant women and their GP when they assess PILs. Phrasing of medicines information texts can influence teratogenic risk perceptions and thereby prescribing of medicines and adherence.

1 Introduction

Studies have shown that between 44 and 85 % of women use medicines during pregnancy [1–4] for chronic, acute or

S. F. Widnes
Faculty of Medicine and Dentistry, Centre for Pharmacy, Department of Clinical Science, University of Bergen, Bergen, Norway

S. F. Widnes (✉) · J. Schjøtt
Regional Medicines Information and Pharmacovigilance Centre (RELIS Vest), Haukeland University Hospital, 5021 Bergen, Norway
e-mail: sofia.frost.widnes@helse-bergen.no

J. Schjøtt
Faculty of Medicine and Dentistry, Department of Clinical Science, University of Bergen, Bergen, Norway

J. Schjøtt
Section of Clinical Pharmacology, Laboratory of Clinical Biochemistry, Haukeland University Hospital, Bergen, Norway

G. E. Eide
Centre for Clinical Research, Haukeland University Hospital, Bergen, Norway

G. E. Eide
Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway

A. G. Granas
Department of Pharmacy and Biomedical Laboratory Sciences, Faculty of Health Sciences, Oslo and Akershus University College, Oslo, Norway

pregnancy-related conditions, motivating a need for medicines information [5]. Medicines information sources frequently used by pregnant women include health care professionals, written material (e.g. patient information leaflets, PILs), family or friends and the Internet [5, 6]. PILs are inserted in each medicine pack and provide information on how to use the medicine, including use in pregnancy and lactation [7]. The PILs are written by pharmaceutical companies in accordance with the summary of product characteristics (SPC), which is approved by medical authorities. Due to the lack of clinical trials with pregnant participants, regulations set by medical authorities and fears of litigation, the companies rarely state that medicines are safe to use in pregnancy in PILs and other product information [8]. Furthermore, PILs have been criticised for having too complex language and not meeting patients' information needs [9, 10].

Among all pregnancies, there is a 2–4 % baseline risk of major birth defects [11]. Although less than 1 % of these can be attributed to the use of medicines, a supposed teratogenic risk of a medicine may result in termination of planned pregnancies or inadequate treatment of pregnant women's disorders [12]. Several studies have found unrealistically high teratogenic risk perceptions among physicians or other health care professionals [13–15] and pregnant women [5, 13, 14, 16–18]. Pregnant women reported even higher risk perceptions compared to physicians [13, 14]. In one study, four variations in wording of a text about the safety in pregnancy for a medicine were presented to pregnant women and health care professionals. The original label for bendectin (Diclectin™) was one of the texts and the other three texts had the same content, but differed in their language and frequency of use of the term "malformations" in title and text. Bendectin was assessed as safe in pregnancy by the authors; however, none of the participants found it safe to use, regardless of which text wording used. However, texts that did not repeatedly use the term "malformations", received the lowest risk score [13]. Based on these study results, wording in written medicines information sources appears to be important for communication of teratogenic risks.

In a clinical situation, the general practitioner (GP) initiates medical therapy in pregnancy, usually after discussing the matter with the woman, and it is important to examine if these two have different views regarding use of medicines. To our knowledge, there are no previous studies of teratogenic risk perceptions and confidence in use of medicines in pairs of pregnant women and GPs. The aim of the present study was to examine differences between pregnant women and their corresponding GPs in teratogenic risk perceptions and confidence in use of medicines during pregnancy, assessed through authentic texts from PILs, and to examine clarity of these medicines information texts.

2 Methods

2.1 Recruitment of Participants

Participants were recruited from the ultrasound laboratory at the Department of Gynaecology and Obstetrics at Haukeland University Hospital in Bergen, Norway. Reception staff handed out questionnaires and letters of information to women attending routine ultrasound examination between weeks 17 and 19 of pregnancy. Women unable to read Norwegian, younger than 18 years or in gestation week different to 17–19 were excluded. The questionnaire was filled in anonymously by the woman and mailed in a pre-stamped envelope or handed in. In the questionnaire, the woman provided the name of her GP and the GP's clinic. A questionnaire was thereafter mailed to the GP, together with an information letter and a pre-stamped envelope. If the GP did not respond within a month, a reminder was sent. Lastly, if no reply was received, the first author called the GP's clinic. To increase response rate, a lottery of a gift voucher was announced in the information letter. Three pregnant women and three GPs each received a gift voucher worth €66.

The questionnaires from the pregnant women and their respective GP were paired. Some women had the same GP; however, the questionnaire was sent only once to each GP. GPs with more than one participating patient were paired with all corresponding patients.

A pilot study was carried out to estimate the number of participants needed in the main study. In the pilot study, the questionnaire was distributed to 50 pregnant women with the same recruitment method as described above. Respondents in the pilot study were included in the main study.

The study was presented for the Regional Committee for Medical Research Ethics, but due to anonymous collection of patient data, approval was not required.

2.2 Data Collection

The pilot study took place from September to November 2010 and the main study from November 2010 to March 2011. The questionnaire contained authentic texts regarding pregnancy from PILs for five medicines and one herbal medicine. Active substances, product names and indications for use, were stated in this order on the questionnaire:

- Pivmecillinam (Selexid™) for urinary tract infection
- Metoclopramide (Afipran™) for pregnancy-induced nausea during the first trimester
- Paracetamol (Paracet™) for back pain
- Escitalopram (Cipralex™) for depression during the first trimester

- Valeriana officinalis (Valerina Natt™) herbal medicine for insomnia
- Dexchlorpheniramine (Polaramin™) for seasonal allergy

The name of the medicine was not stated, but each text was introduced with a case description. For example: "envisage getting a urinary tract infection and your GP prescribing an antibiotic for this. The patient information leaflet says: (text from the PIL)".

The texts from the PILs were identical for women and GPs, though the case descriptions were targeted to patient (taking a prescribed or advised medicine) or GP (prescribing a medicine at indication), respectively. Figure 1 presents the translated texts from the PILs included in the questionnaire. Each text was followed by three questions:

- Question A: how teratogenic do you consider this medicine to be? (Scale from 0: never teratogenic to 10: always teratogenic)
- Question B: are you confident in taking (pregnant women) or prescribing (GPs) this medicine? (yes or no). For the herbal medicine, the GP was asked whether he or she would recommend use or not.

Fig. 1 Translated texts from patient information leaflets as given on the questionnaire

Pivmecillinam (Selexid™) for urinary tract infection

Consult a physician or pharmacy before taking any kind of medicine.
Long experience when using Selexid during pregnancy has not shown any harmful effects. Caution should be taken when treating pregnant women for a longer period (more than 2 weeks) due to the risk of developing carnitine depletion.

*Carnitine depletion can give muscular weakness

Metoclopramide (Afipran™) for pregnancy-induced nausea :

Consult a physician or pharmacy before taking any kind of medicine.
The risk of use in pregnancy is small. No teratogenic effects have been observed after use of this medicine against nausea in pregnancy. Other types in the same group of medicines have given long-lasting, reversible neurological disturbances of the child, when given in high doses in the third trimester. This medicine should therefore not be used in the last trimester.

Paracetamol (Paracet™) for back pain:

Consult your doctor or pharmacy before taking any medicine.
Long experience with use of this medicine during pregnancy has not shown adverse effects. Consult your doctor before using this medicine if you are pregnant.

Escitalopram (Cipralex™) for depression:

Inform your doctor if you are pregnant or planning to become pregnant. Do not take Cipralex if you are pregnant or breast-feeding unless you and your doctor have discussed the risks and benefits involved.

If you take Cipralex during the last 3 months of your pregnancy you should be aware that the following effects may be seen in your newborn baby: trouble with breathing, blue-ish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. If your newborn baby has any of these symptoms, please contact your doctor immediately. If used during pregnancy, Cipralex should never be stopped abruptly.

Valeriana officinalis (Valerina Natt™) for sleep difficulties:

Should not be used by pregnant or breast feeding women as the risks of use in pregnancy and breast feeding are unknown.

Dexchlorpheniramine (Polaramin™) for seasonal allergy:

No unfavourable effects on the foetus have been shown.

Table 1 Personal characteristics of the responding 74 general practitioners (GPs) and 171 pregnant women

	n	%
GPs (n = 74)		
Mean age (range)	44.8 (27–65)	
Mean no of years in practice (range)	16.4 (1–40)	
Sex		
Female	37	50.0
Male	37	50.0
Pregnant women (n = 171)		
Mean age (range)	29.5 (20–42)	
Parity (n = 170)		
0	79	46.5
1	58	34.1
2	31	18.2
3	2	1.2
Smoking status		
Yes	4	2.3
No	167	97.7
Level of education		
Basic school level	1	0.6
Upper secondary education	46	26.9
Tertiary education	124	72.5
Folic acid supplement in pregnancy		
Yes	166	97.1
No	5	2.9
Medication-treated chronic disease		
Yes	16	9.4
No	155	90.6
Medication-treated mild symptoms		
Yes	51	29.8
No	120	70.2
Use of herbal medicines		
Yes	12	7.0
No	159	93.0

- Question C: how clear do you perceive the content of the text to be? (Scale from 0: exceptionally clear to 3: exceptionally unclear)

The participants were asked to provide some personal characteristics as presented in Table 1.

2.3 Data Analysis

The null hypothesis was that teratogenic risk perceptions and confidence in use of medicines did not differ between pregnant women and their GPs. We considered the least clinical significant difference between pregnant women and GPs assessing teratogenic risk to be two units on the risk scale span from 0 to 10 (question A). Based on the pilot study, 36 pairs were estimated as the minimal requirement to test the null hypothesis with 90 % power.

Teratogenic risk score (question A) was analysed as a response variable on type of responder (pregnant woman or GP) with a mixed linear model analysis [19], accounting for dependency between women and GPs. For question B, we used logistic regression of confidence in use of medicines on type of responder. Clarity of the text (question C) was analysed as a response variable on type of responder with an ordinal logistic regression. To control for correlated data, the logistic regressions of questions B and C were performed with generalized estimating equations [20].

The analysis of influence of personal characteristics on response variables (questions A and B) was performed separately for pregnant women and GPs. All variables presented in Table 1 were included, and the analysis was performed with multiple linear (question A) and logistic (question B) regression.

To analyse the relationship between scores for teratogenic risk (question A) and non-confidence in use of a medicine (question B), we used simple logistic regression of the latter on the former. Results are presented as odds ratios (OR) and 95 % confidence intervals (CI). P-values ≤ 0.05 were accepted as statistically significant. SPSS version 18 (SPSS, Chicago, IL, USA) was used for data analysis.

3 Results

Figure 2 presents flow charts for the recruitment process in the pilot and main study. A total of 300 questionnaires were handed out to pregnant women and 175 responded (response rate 58 %). Four responses were excluded because they were in gestation week different to 17–19, giving a sample of 171 pregnant women. These women had a total of 121 different GPs, of whom two were excluded due to long-term sick leave or emigration, and 74 GPs responded (62 % response rate). Since some of the women had the same GP, a total of 98 pairs of pregnant women and GPs were identified. For the remaining 73 pregnant women, the corresponding GP did not reply. Personal characteristics of the participants are given in Table 1.

In Table 2, the text assessments by the 171 pregnant women, the 74 GPs and all 245 participants are described, both for each of the six texts individually, and for all texts combined. Both pregnant women and GPs assessed the teratogenic risks of the texts for escitalopram and Valeriana officinalis highest and confidence in use of these medicines was the lowest. None of the participants had confidence in use of the herbal medicine Valeriana officinalis. The texts for paracetamol and dexchlorpheniramine were assessed

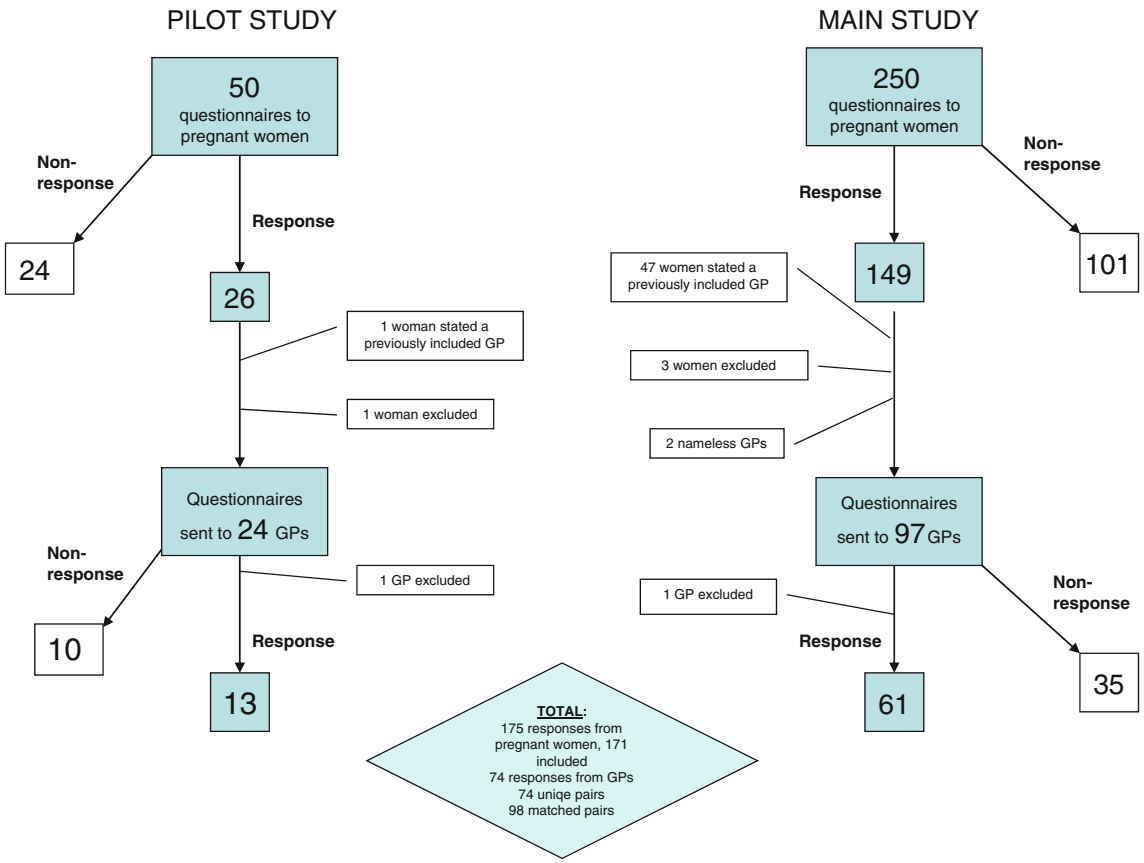

Fig. 2 Flow charts for the process of recruitment. *GP* general practitioner

the least teratogenic and were associated with high confidence in use of the medicine. Among all participants, there were only minor differences in the overall score of clarity of all texts, except for GP's assessment of the text for escitalopram as less clear than the other texts.

In Table 3, the assessments by the 98 pairs of pregnant women and GPs are compared. The pregnant women assessed the teratogenic risks significantly higher than the corresponding GPs for all six texts. The differences between assessments of texts for escitalopram (mean difference: −3.3), Valeriana officinalis (mean difference: −2.4) and metoclopramide (mean difference: −2.1) were clinically significant according to our definition of minimum 2 units difference. Table 3 shows that GPs had significantly more confidence in prescribing the medicines than the pregnant women had in taking them. For escitalopram, it was 9.5 times more likely for the GP to have confidence in prescribing the medicine compared to the pregnant woman's confidence in taking it. In comparison, the corresponding OR for dexchlorpheniramine was 2.8. Table 3 also shows that pregnant women found the text for escitalopram to be significantly clearer than GPs did.

Multiple linear and logistic regression analysis showed no consistent trends in personal characteristics' influence on teratogenic risk assessments or confidence in taking or prescribing medicines.

In the logistic regressions of non-confidence on teratogenic risk scores, the ORs varied from 2.0 (95 % CI 1.6–2.5) for pregnant women's assessment of pivmecillinam, and upwards. The regressions were statistically significant for all texts assessed by GPs and pregnant women respectively, except for Valeriana officinalis since none of the participants had confidence in the use of it.

4 Discussion

The present study is the first to examine teratogenic risk perceptions and confidence in the use of medicines in pairs of pregnant women and GPs through assessments of medicines information texts from PILs. Our main finding was that pregnant women had higher teratogenic risk perceptions and lower confidence in use of medicines than their corresponding GP. Responses of these two parameters were also found to be correlated. Although other studies examining teratogenic risk perception have not included pairs, we find support for our findings [13, 14]. Importantly, we used authentic texts from PILs as a tool, based

Table 2 Assessment of texts from patient information leaflets of six medicines by all 245 participants (171 pregnant women, 74 GPs)

Texts for respective medicine	Teratogenic risk[a]		Confidence in taking or prescribing the medicine[b]		Clarity of the text[c]	
	Mean	Range	Mean	Range	Mean	Range
Escitalopram						
All participants	6.1	0–10	0.8	0–1	1.1	0–3
GPs	3.7	0–8	0.5	0–1	1.5	0–3
Pregnant women	7.2	0–10	0.9	0–1	0.9	0–3
Valeriana officinalis						
All participants	6.1	0–10	1.0	0	1.0	0–3
GPs	4.3	0–10	1.0	0	0.8	0–3
Pregnant women	6.9	0–10	1.0	0	1.0	0–3
Metoclopramide						
All participants	3.1	0–10	0.3	0–1	1.1	0–3
GPs	1.5	0–10	0.1	0–1	1.0	0–2
Pregnant women	3.8	0–10	0.4	0–1	1.2	0–3
Pivmecillinam						
All participants	2.7	0–10	0.2	0–1	1.0	0–3
GPs	1.5	0–10	0.0	0–1	0.8	0–3
Pregnant women	3.3	0–10	0.3	0–1	1.1	0–3
Paracetamol						
All participants	2.3	0–10	0.2	0–1	0.9	0–3
GPs	1.3	0–10	0.1	0–1	0.9	0–3
Pregnant women	2.7	0–8	0.3	0–1	1.0	0–3
Dexchlorpheniramine						
All participants	1.8	0–10	0.2	0–1	0.9	0–3
GPs	1.0	0–5	0.1	0–1	0.7	0–3
Pregnant women	2.2	0–10	0.3	0–1	1.0	0–3
Combined assessments of all texts						
All participants (n = 245)	3.7		0.5		1.0	
GPs (n = 74)	2.2		0.3		0.9	
Pregnant women (n = 171)	4.3		0.5		1.0	

GP general practitioner

[a] Scale from 0 to 10 where 0: never teratogenic and 10: always teratogenic

[b] Scores: 0: yes, 1: no

[c] Scores: 0: exceptionally clear, 1: rather clear, 2: rather unclear, 3: exceptionally unclear

on other findings that formulations of medicines information can influence teratogenic risk perceptions [13].

The clinically significant differences in teratogenic risk assessments of the texts for escitalopram, Valeriana officinalis and metoclopramide, in addition to significant differences in the confidence to use these medicines, indicate consequences for therapeutic decision making and adherence to therapy [21]. The result may be suboptimal treatment of pregnant women or abortion of otherwise wanted children [22].

There are several possible explanations for the observed differences among pregnant women and GPs. Media have a tendency to stress risks rather than benefits of medicines, and pregnancy imposes an increased sensitivity to risks [23, 24]. One example is that media attention in 2004 regarding the possible harmful effects on the baby of using selective serotonin reuptake inhibitors (SSRIs) during pregnancy increased the number of calls from concerned women to a teratology information service (TIS) [25]. To our knowledge, there was no media focus on teratogenic effects of any of the included medicines close up to or during the period of data collection. However, previous media attention to harmful effects of antidepressants in pregnancy may have affected the risk perception of escitalopram.

In decisions on medicines use, a pregnant woman may assess risk subjectively, based on personal experiences, influence of family and friends, norms and expectations of

Table 3 Comparison of assessments of information texts from patient information leaflets by pairs of pregnant women and GPs (n = 98)

Text	Teratogenic risk[a]		Confidence in taking or prescribing the medicine[b]		Clarity of the text[c]	
	GPs vs pregnant women		GPs vs pregnant women		GPs vs pregnant women	
	Mean difference	95 % CI	OR[d]	95 % CI	OR[e]	95 % CI
Escitalopram	−3.3*[f]	−4.1, −2.6	9.5*	3.4, 23.4	4.0*	2.3, 6.7
Valeriana officinalis	−2.4*[f]	−3.1, −1.7	All participants responded No		0.9	0.5, 1.8
Metoclopramide	−2.1*[f]	−2.8, −1.4	4.0*	1.8, 8.9	1.0	0.5, 1.7
Pivmecillinam	−1.8*	−2.4, −1.3	10.0*	2.9, 34.7	0.5*	0.3, 0.9
Paracetamol	−1.4*	−2.0, −0.9	4.9*	2.0, 11.9	0.8	0.5, 1.5
Dexchlorpheniramine	−1.0*	−1.5, −0.5	2.8*	1.2, 6.5	0.5*	0.3, 0.9

All analysis were adjusted for matched pairs using mixed linear model (teratogenic risk) or general estimating equations

CI confidence interval, *GP* general practitioner, *OR* odds ratio, * indicates significant difference between pregnant women and GPs ($p \leq 0.05$)

[a] Scale from 0 to 10, where 0: never teratogenic and 10: always teratogenic

[b] Scores: 0: yes, 1: no

[c] Scores: 0: exceptionally clear, 1: rather clear, 2: rather unclear, 3: exceptionally unclear

[d] From binary logistic regression model

[e] From proportional odds model

[f] Clinically significant difference according to our definition: minimum mean difference of 2

being a "good mother" [21, 26]. Pregnant women may also consider their own benefits of treatment to be irrelevant compared to the slightest possibility of risk to the foetus [27]. Health care professionals, on the other hand, may evaluate risk in a more objective manner [28]. Physicians also aim to minimize the risk of harm to the foetus; however, their primary focus is on weighing benefits and risks for patients [21]. Pregnant women and GPs' different ways of assessing risks may therefore contribute to explain the findings. The observed differences may also be due to different interpretations of the texts from the PILs. The text for escitalopram was associated with much lower confidence in use among pregnant women than GPs. A reason for this difference may be that the text for escitalopram was the most extensive and detailed of the six texts, describing possible effects on newborns after exposure during the last trimester. This is in line with other findings that texts frequently referring to foetal effects may increase concern among pregnant women [13]. In contrast, GPs may consider general symptoms such as "jitteriness, irritability, lethargy, and constant crying" (Fig. 1) to be general symptoms that may be unrelated to maternal antidepressant use. It has also been shown that GPs consider extensive texts with detailed information to be less useful for patients [29], preferring written patient information to be brief and simple [9]. This may also explain why GPs considered the text for escitalopram to be less clear than the other texts.

We have included texts for six medicines which have different indications and are intended for short- or long-term treatment. This resulted in different assessments of teratogenic risks and confidence in use for the different medicines, as presented in Table 2. Our results are supported by suggestions that medicines information texts can have an impact on knowledge, attitudes and behaviour of medicine users [9]. Teratogenic risk assessment among all participants was highest for the texts for escitalopram and Valeriana officinalis and lowest for dexchlorpheniramine, representing texts with different phrasing and length. The text for Valeriana officinalis advises against use, based on the sparse documentation for safety of herbal medicines in pregnancy [30], while the text for dexchlorpheniramine conveys safe use. The high teratogenic risk score for escitalopram may reflect the fact that antidepressants are associated with possible risks for teratogenic effects [31]. The anticipated long-term use of escitalopram, as opposed to short-term use of, for example, antihistamines and antibiotics, may also have influenced teratogenic risk perceptions. Further reasons for low confidence in escitalopram could be excessive focus on stigma related to depression and antidepressants, underrating the negative health effects of untreated depression [22, 32].

Another possible explanation for the differences found could be that the pregnant women failed to understand the language used in the texts from the PILs or in the instructions given on the questionnaire. For example, the term "teratogenic" could leave room for different interpretations. However, on the questionnaire, we used the Norwegian public term for teratogenic: "fosterskadelig", i.e. "harmful to the foetus", which is used in everyday language, to ensure that the information was understood.

We found no influence of pregnant women's or GPs' personal characteristics on their teratogenic risk

perceptions. It could be hypothesized that increased work experience among GPs could imply a greater confidence in assessing teratogenic risks independently of the information texts, but our data did not reveal such a connection.

4.1 Implications for Practice

Teratogenic risk perceptions and confidence in the use of medicines may have implications for prescribing of medicines and adherence to prescriptions in a clinical setting. Since differences in risk perceptions may be a barrier to communication [33], health care professionals need to understand the perceptions of their pregnant patients to discuss risks and benefits of treatment options [24]. We suggest that GPs inform about the inherent restrictiveness of information regarding pregnancy in PILs, thereby reducing unrealistic teratogenic risk perceptions and possibly improving adherence. Furthermore, based on the findings indicating that the wording in information texts can increase or reduce concerns for teratogenic effects, the results could be of importance for future design of PILs and for medicines information in pregnancy in general.

4.2 Methodological Considerations

We have examined teratogenic risk perceptions in pairs of pregnant women and GPs. Furthermore, confidence in use of medicines was based on hypothetical case descriptions (with condition or indication) as a surrogate for a clinical situation. We believe that by measuring both A: risk perceptions, B: the clinical consequence (confidence in use of medicines) and C: clarity of the information text for which the assessments of A and B were made, we achieved a better understanding of the attitudes to medicines use in pregnancy. Importantly, scores for teratogenic risk (question A) and confidence in use of the medicine (question B) were correlated, showing that indicators of perception and behaviour were associated in our results. This strengthens our interpretation that if a situation where medical therapy is needed would arise during pregnancy, differences in risk perception within the pair could be of importance for therapeutic decisions and adherence.

The response rate was about 60 % in both groups and survey respondents may differ from non-responders regarding assessments of the texts. However, the women were recruited consecutively from the ultrasound laboratory of a University Hospital, without selection of participants, and the age distribution of the participants was similar to that in the general population of women giving birth in Norway [34]. Nevertheless, the level of education and proportion of women using folic acid was higher, and the proportion of smokers and users of herbal medicines lower among the participants compared to the general population in Norway. This may have influenced the results, based on findings from a Norwegian study that a higher educational level may be associated with increased teratogenic risk perceptions [5]. However, it has been shown that persons with a high level of education and good health are more declined to participate in surveys compared to those with a lower education level and poor health [35], and participation in our study follows this pattern.

The texts chosen for the questionnaire may have affected the results. However, the medicines included are commonly used in pregnancy. A possible confounding factor was that the indications (for example depression) were assessed instead of the texts. However, by only providing the indication, we reduced the risk for preconceptions about teratogenic risks associated with certain medicines or branded names.

Texts from PILs were used as the assessment tool. This is a source intended for patients and the corresponding source of information for health care providers is the SPC. However, in order to directly compare the answers from women and GPs, the texts had to be identical, requiring use of a patient information source as the assessment tool.

To calculate the minimal required number of participants, we predefined the least clinical difference between pregnant women and GPs to be two units on the teratogenic risk scale (0–10). In support of this definition, the average clinically significant difference on a pain intensity numerical rating scale from 0 to 10 has been found to be two points [36].

5 Conclusions

Pregnant women had higher teratogenic risk perceptions and lower confidence in use of medicines than their corresponding GPs, based on assessment of medicines information texts from PILs. Health care professionals should be aware of these differences, as it may influence patients' adherence to prescribed or recommended medicines for conditions in need of treatment or the tendency to end the pregnancy. Our results indicate that phrasing of medicines information can influence teratogenic risk perceptions and confidence in medicines use. We suggest that GPs discuss the texts in the PILs with pregnant women to prevent unfounded concerns about drug therapy that may arise due to the limitations of the teratogenic information provided in PILs.

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